REMARKS

A. Response to restriction requirement

In the Restriction Requirement, the Examiner alleged that the pending claims comprised sixteen (16) patentably distinct inventions, as detailed on pages 2-4 of the Action.

Regarding the factors necessary to sustain a restriction requirement, Applicant notes that *MPEP* section 803 states, *inter alia*, that:

> There are two criteria for a proper requirement for restriction between patentably distinct inventions:
> (A) The inventions must be independent [ ]; and
> (B) There must be a serious burden on the examiner if the restriction is required...

Moreover, in the same section, the MPEP pointedly states that: "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." *Id.* (emphasis added)

It is Applicant's position that, as currently drafted, the restriction requirement does not establish a *prima facie* case that the present Restriction meets the "serious burden" requirement. It is, therefore, Applicant's position that all, or at a minimum more than one of the groups designated by the Examiner as Groups I-XII should be examined together.

Regarding the examination of multiple species in a Markush group, the MPEP states that:

> [i]f the members of the Markush group are sufficiently few in number or so closely related that the search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.

MPEP §803.02.

Accordingly, Applicant believes that the restriction requirement should be withdrawn, or at least modified in accordance with the following suggestions, because there are "sufficiently

few members" of the Markush group which can be examined without "serious burden." Furthermore, the members of this Markush group are constituted of "species" of one or more generic claims and will therefore, as the Examiner indicated, have to be examined in so far as they are included as part of claims depending from an allowed generic claim.

Furthermore, Applicant would like to draw the Examiner's attention to the fact that all of the claimed peptides were designed (using molecular modeling and computational chemistry) and constructed to have generic properties which include a three-dimensional structure which mimics the immunogenic determinants of self-proteins recognized by autoimmune antibodies (*see* specification pages 11-13). Moreover, two structural features, shared by all of the claimed peptides, are believed to be key to their recognition by the autoimmune antibodies. The first feature is a "peptide turn" comprising at least one citrulline residue and the second feature is the presence of 2 cysteine residues which are separated by less than 12 amino acids, wherein the citrulline residue is one of the amino acids located between these two cysteine residues (*see* claim 1).

Additionally, Applicant contends that there is no legitimate basis for restricting out the "cyclic" and "linear" peptides in the present application. It is Applicant's position that the examination of cyclic peptides can be accomplished in the same application as linear peptides, without serious burden on the Examiner. Absent a showing by the examiner to the contrary, Applicant asserts that, as a practical matter, any search(es) performed to determine the patentability of the linear sequence peptides would be co-extensive with a sequence search(es) for the circular peptide(s). Therefore, Applicant believes that no additional search(es) is/are required and that no serious burden would be imposed on the Examiner by examining, in the instant application, both the linear and circular peptides.

In view of the foregoing arguments, Applicant respectively requests that the instant restriction requirement be withdrawn, or alternatively, modified to allow examination of at least groups I-XII in the present application.

Furthermore, even if the Examiner is able to provide evidence refuting the arguments presented above, as an alternative to the examination of groups I-XII, in the present application, Applicant respectfully requests that the Examiner consider examining one of the following two "alternative" groups:

Alternative Group 1: claims 1, 3-9, 12-15, and 18-22 drawn to circular peptides with an amino acid structure as defined in claim 1 and compositions thereof; a kit comprising said peptide; and an immunotoxin comprising said peptide and compositions thereof.

Alternative Group 2: claims 1, 3-9, 12-15, and 18-22 drawn to circular peptides with an amino acid structure as defined by SEQ ID NO:4, 5, or 6 and compositions thereof; a kit comprising said peptide; and an immunotoxin comprising said peptide and compositions thereof.

By way of explanation, "alternative group 1" corresponds to groups VII-XII (as defined by Examiner in the Restriction Requirement), whereas "alternative group 2" corresponds to groups X-XII (as defined by Examiner in the Restriction Requirement) and is directed to "type II" peptides. As noted in the specification, at page 7, lines 7-9, type II peptides, as defined by the instant invention, are those peptides having 4 amino acids between the two cysteine residues.

In summary, in view of the requirements of MPEP §§ 803 and 803.02 it is Applicant's position that, at a minimum, all claims represented by Examiner's Group I –XII should be examined concomitantly in the present application. Applicant asserts that examination of these

claims together in the present application does not present a "serious burden," to the Examiner, and is therefore required under MPEP § 803.

Notwithstanding the foregoing arguments, in response to the restriction requirement, Applicant elects, with traverse, to prosecute claims 1-9, 12-15 and 18-22, drawn to a cyclic peptide comprising the primary amino acid structure of SEQ ID NO:4, a composition thereof and immunotoxin comprising said peptide(s) and composition thereof, and a kit comprising said peptide, *i.e.*, the Group X claims. Furthermore, pursuant to Examiner's requirement in paragraph "8." of the Office Action, Applicant provisionally elects SEQ ID NO:12. As required by the Examiner, Applicant notes that claims 1-9, 12-15 and 18-22 all read on this elected species.

Finally, Applicant specifically acknowledges paragraph "11." of the Office Communication, which summarizes the content of MPEP § 809.02(c)(B)(1) (this section mandates that, upon allowance of a generic claim, Applicant will be entitled to examination of claims to a reasonable number of non-elected species, so long as they are written in dependent form).

The Examiner is invited to contact the undersigned patent agentat (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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